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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:	:	
Fosamax Products Liability Litigation	:	1:06-md-1789 (JFK)
	:	
This Document Relates to:	:	**ANSWER AND AFFIRMATIVE**
Stacey Hall	:	**DEFENSES OF MERCK**
v. Merck & Co., Inc.	:	**& CO., INC.;**
	:	**DEMAND FOR JURY TRIAL**
Case No: 1:08-cv-03504-JFK	:	

Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

INTRODUCTION

Merck denies each and every allegation made in the Introduction, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and that Plaintiff purports to bring a civil action for damages, but denies that there is any legal or factual basis for the same. Merck respectfully refers the Court to the Physicians' Desk Reference ("PDR") for FOSAMAX® for its actual language and full text and denies any allegations in the Introduction inconsistent with that prescribing information.

JURISDICTION AND VENUE

1. The allegations contained in Paragraph 1 are conclusions of law to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in Paragraph 1, except that for jurisdictional purposes only, admits that the amount in controversy exceeds $75,000.

GENERAL ALLEGATIONS

2. Merck denies each and every allegation of Paragraph 1, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and that Plaintiff purports to bring a civil action for damages, but denies that there is any legal or factual basis for the same. Further, Merck states that it is without knowledge as to whether Plaintiff has been prescribed or ingested FOSAMAX®.

3. Merck denies each and every allegation of Paragraph 3.

4. Merck denies each and every allegation of Paragraph 4, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

5. Merck admits that it is registered to do business in the State of California.

6. Merck denies each and every allegation of Paragraph 6.

7. Merck denies each and every allegation of Paragraph 7.

8. Merck denies each and every allegation of Paragraph 8.

THE PARTIES

The Plaintiff

9. Merck denies each and every allegation of Paragraph 9, except to state that Merck is without knowledge as to the residence of Plaintiff and whether she took FOSAMAX®.

The Defendants

10. Merck denies each and every allegation of Paragraph 10, except that it admits that it is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in Whitehouse Station, New Jersey, and admits that it is registered to do business in California.

11. Merck denies each and every allegation of Paragraph 11, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information. Merck further states that it is without knowledge as to whether Plaintiff ingested FOSAMAX®.

FACTUAL BACKGROUND

12. Merck denies each and every allegation in Paragraph 12, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 12 inconsistent with that prescribing information and respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text.

13. Merck denies each and every allegation of Paragraph 13, except that Merck admits that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 13 inconsistent with that prescribing information and respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text, including its sections on pharmacodynamics and mechanism of action.

14. The allegations of Paragraph 14 merely restate information taken from the website of the National Osteoporosis Foundation and are not directed at Merck. Consequently, no response is required. To the extent a response is required, Merck states that the statistics presented on the National Osteoporosis Foundation website speak for themselves, and Merck denies any allegation of Paragraph 14 directed to Merck.

15. The allegations of the first sentence Paragraph 15 merely restate information taken from the website of Business Week Online and are not directed at Merck. Consequently, no response is required. To the extent a response is required, Merck states that the information presented on the Business Week Online website speaks for itself, and Merck denies any allegation of the first sentence of Paragraph 15 directed to Merck. Merck denies each and every allegation of the second sentence of Paragraph 15, except it admits that in 2005, Merck reported that FOSAMAX® recorded the second highest sales in its line of therapeutic and preventative agents and admits that FOSAMAX® is the most prescribed medicine for the treatment of postmenopausal, male and glucocorticoid-induced osteoporosis.

16. The allegations of the first two sentences of Paragraph 16 merely restate information taken from the website of IMS Health. Consequently, no response is

required. To the extent a response is required, Merck states that the information presented on the IMS Health website speaks for itself, and Merck denies any allegation of the first two sentences of Paragraph 16 directed to Merck. As to the allegations of the third sentence of Paragraph 16, Merck states that the information presented on the Consumer Reports website speaks for itself, and Merck denies any allegation of the third sentence of Paragraph 16 directed to Merck. Merck denies each and every allegation of the fourth sentence of Paragraph 16, except admits that it obtained approval from the FDA for FOSAMAX PLUS D® in 2005 and admits that the language quoted therein appears in Merck's 2005 Annual Report.

17. Merck admits only that some bisphosphonates contain nitrogen and some do not and denies all remaining allegations of Paragraph 17.

18. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 18 inconsistent with that prescribing information and respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck denies any remaining allegations of Paragraph 18.

19. Merck denies each and every allegation of Paragraph 19.

20. Merck denies each and every allegation of Paragraph 20.

21. Merck denies each and every allegation of Paragraph 21.

22. Merck denies each and every allegation of Paragraph 22.

23. Merck denies each and every allegation of Paragraph 23.

24. Merck denies each and every allegation of Paragraph 24, except that Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but respectfully refers the Court to said document for its actual language and full text.

25. Merck denies each and every allegation of Paragraph 25, except that Merck admits that on January 31, 2005, it received a request dated January 24, 2005 from the FDA to update the label for FOSAMAX® to include bisphosphonate class labeling for ONJ. Merck submitted a draft revised label to the FDA on March 1, 2005. FDA comments on this draft revised label were received in June 2005, and the new label was made publicly available in July 2005.

26. Merck denies each and every allegation of Paragraph 26.

27. Merck denies each and every allegation of Paragraph 27.

28. Merck denies each and every allegation of Paragraph 28, except to state that Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX® by her physician and whether Plaintiff ingested FOSAMAX® as prescribed and in a foreseeable manner.

29. Merck denies each and every allegation of Paragraph 29.

30. Merck denies each and every allegation of Paragraph 30.

31. Merck denies each and every allegation of Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32.

FIRST CLAIM FOR RELIEF

STRICT LIABILITY – FAILURE TO WARN

33. Merck repleads its answers to all preceding Paragraphs above, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

34. Merck denies each and every allegation of Paragraph 34, except that it admits that Merck manufactured and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

35. Merck denies each and every allegation of Paragraph 35.

36. Merck denies each and every allegation of Paragraph 36.

37. Merck denies each and every allegation of Paragraph 37.

38. Merck denies each and every allegation of Paragraph 38, including each and every allegation of subparts (a) through (c).

SECOND CLAIM FOR RELIEF

NEGLIGENCE

39. Merck repleads its answers to all preceding Paragraphs above, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

40. The allegations in Paragraph 40 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42, including each and every allegation of subparts (a) through (e).

43. Merck denies each and every allegation of Paragraph 43.

44. Merck denies each and every allegation of Paragraph 44.

45. Merck denies each and every allegation of Paragraph 45.

THIRD CLAIM FOR RELIEF

FOR BREACH OF IMPLIED WARRANTY

46. Merck repleads its answers to all preceding Paragraphs above, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

47. Merck denies each and every allegation of Paragraph 47, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

48. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 48.

49. Merck denies each and every allegation of Paragraph 49.

50. Merck denies each and every allegation of Paragraph 50.

51. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 51.

52. Merck denies each and every allegation of Paragraph 52.

53. Merck denies each and every allegation of Paragraph 53.

FOURTH CLAIM FOR RELIEF

FOR BREACH OF EXPRESS WARRANTY

54. Merck repleads its answers to all preceding Paragraphs above, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

55. Merck denies each and every allegation of the first sentence of Paragraph 55, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck is without knowledge or information sufficient to form a belief as to the truth of falsity of the allegations of the second sentence of Paragraph 55.

56. Merck is without knowledge or information sufficient to form a belief as to the truth of falsity of the allegations of the first sentence of Paragraph 56. Merck denies each and every allegation of the second sentence of Paragraph 56, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

57. Merck denies each and every allegation of Paragraph 57.

58. Merck denies each and every allegation of Paragraph 58.

FIFTH CLAIM FOR RELIEF

DECEIT BY CONCEALMENT

59. Merck repleads its answers to all preceding Paragraphs above, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

60. Merck denies each and every allegation of Paragraph 60.

61. Merck denies each and every allegation of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

63. Merck denies each and every allegation of Paragraph 63.

64. Merck denies each and every allegation of Paragraph 64.

65. Merck denies each and every allegation of Paragraph 65.

SIXTH CLAIM FOR RELIEF

NEGLIGENT MISREPRESENTATION

66. Merck repleads its answers to all preceding Paragraphs above, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

67. Merck denies each and every allegation of Paragraph 67.

68. Merck denies each and every allegation of Paragraph 68.

69. Merck denies each and every allegation of Paragraph 69.

70. Merck denies each and every allegation of Paragraph 70.

71. Merck denies each and every allegation of Paragraph 71.

72. Merck denies each and every allegation of Paragraph 72.

PUNITIVE DAMAGES ALLEGATIONS

(As to the First, Second, Fifth, and Sixth Claims for Relief, only)

73. Merck repleads its answers to all preceding Paragraphs above, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

74. Merck denies each and every allegation of Paragraph 74.

75. Merck denies each and every allegation of Paragraph 75.

76. Merck denies each and every allegation of Paragraph 76.

77. Merck denies each and every allegation of Paragraph 77.

Merck denies that Plaintiff is entitled to any of the relief requested in her Prayer for relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims

and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations, doctrine of prescription, and/or is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

EIGHTH AFFIRMATIVE DEFENSE

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault.

NINTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recovery for strict liability because Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded

any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States, Alabama, and New York Constitutions.

THIRTIETH AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff has not suffered any actual injury or damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens.*

FORTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims of fraud are not pleaded with the required particularity.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff cannot recover for the claims asserted because Plaintiff has failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of warranty are barred because Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

FORTY-THIRD AFFIRMATIVE DEFENSE

An asymptomatic plaintiff lacks standing because she has suffered no damages and no injury-in-fact.

FORTY-FOURTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

FORTY-FIFTH AFFIRMATIVE DEFENSE

The substantive law of Alabama applies to Plaintiff's claim.

FORTY-SIXTH AFFIRMATIVE DEFENSE

Merck affirmatively pleads that any punitive damages that the Plaintiff may recover in this case should be capped in keeping with Alabama Code Section 6-11-21, as

amended in 1999 (Act. No. 99-358) and in the spirit of the Alabama Supreme Court's decision in *Oliver v. Towns*, 738 So. 2d 798 (Ala. 1999).

FORTY-SEVENTH AFFIRMATIVE DEFENSE

The demand for punitive damages in the instant case is subject to the limitations established by the Alabama legislature and set forth in Ala. Code § 6-11-21 (1975). Merck adopts by reference the defenses, criteria, limitations, and standards mandated by this Alabama statute. The Alabama Supreme Court's action in abolishing the legislatively created cap on punitive damages was unconstitutional and is without effect. Under the Constitutions of the United States and the State of Alabama, the Alabama Supreme Court cannot abolish the cap created by the legislature on punitive damages through this judicial decision. *See Honda Motor Co., Ltd. v. Oberg*, 512 U.S. 415, 114 S. Ct. 2331, 2340 n.9 (1994).

FORTY-EIGHTH AFFIRMATIVE DEFENSE

Merck avers that the punitive damage cap set out in Ala. Code § 6-11-21 (1975) applies to the instant case. *See Horton Homes, Inc. v. Brooks*, 832 So. 2d 44 (Ala. 2001).

FORTY-NINTH AFFIRMATIVE DEFENSE

Merck avers that the method of imposing punitive damages violates Amendment 328, Section 6.11 of the Constitution of Alabama, which prohibits the use of a procedural rule to abridge, enlarge, or modify the substantive right of any party. See *Leonard v. Terminix Int'l Co.*, 854 So. 2d 529 (Ala. 2002).

FIFTIETH AFFIRMATIVE DEFENSE

The imposition of punitive damages is an act of policy making on the part of the judiciary, in violation of Article III, Section 43 of the Constitution of Alabama.

FIFTY-FIRST AFFIRMATIVE DEFENSE

Under Alabama products liability law, Plaintiff has failed to state any claim against the pharmaceutical sales representative defendants.

FIFTY-SECOND AFFIRMATIVE DEFENSE

Pharmaceutical sales representatives are not "sellers" under the Alabama Extended Manufacturers' Liability Doctrine, and therefore cannot be held liable under a theory of strict liability or breach of warranty.

FIFTY-THIRD AFFIRMATIVE DEFENSE

Under Alabama law, no duty to warn runs from a pharmaceutical sales representative to the Plaintiff's prescribing physician.

In so much as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York
May 14, 2008

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: /s/
Norman C. Kleinberg
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Attorneys for Defendant Merck & Co., Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of May, 2008, I caused a copy of the foregoing ANSWER AND AFFIRMATIVE DEFENSES OF MERCK & CO., INC. to be served via first-class mail, postage prepaid, on the following:

GANCEDO & NIEVES LLP
Hector G. Gancedo
Tina B. Nieves
418 N. Fair Oaks Avenue, Suite 202
Pasadena, California

The above addresses have appeared on the prior papers in this action as the office address of the attorneys for Plaintiff.

Deponent is over the age of 18 years and not a party to this action.

I further certify under penalty of perjury that under the laws of the United States of America the foregoing is true and correct.

Executed on May 14, 2008

/s/
Shawn McEnnis